

REMARKS

The Non-Final Office Action issued by the Examiner and the citations referred to in the Office Action have been carefully considered.

This Non-Final Office Action crossed in the mail with the Preliminary Amendment filed July 7, 2008.

In that amendment, the issues now raised by the Examiner have been resolved. The claims submitted there, should be the claims considered as being in response the present Office Action.

Reconsideration is respectfully requested. For completion the substance of the response is repeated for completion.

Clarification has been made in the claims relating to the issues raised by the Examiner under 35 USC 112. There is support for these changes and no issues or new matter arise. (Specification, page 5, lines 17-19; page 6, line 21 through page 7, line 1).

The amended claims are directed to components for use in an assay assembly. As such only portions of the assay strip and the wicking are claimed.

Variously in the different claims there are the following features:

- an overlapped portion of the wicking portion and the assay strip portion
- thereafter flows upwards in the assay strip,
- in use, the container is in an upright position with a top through which urine is introduced into the container,
- in use the action of the urine consists of wicking solely upwardly along the wicking portion in an upward direction in the container from the base towards the top.

More specifically each claim needs to be considered for what it specifically covers: Thus the claimed **components** are as follows:

Independent claim 67 relates to **components** for use in an assay assembly for chemically analyzing a urine sample, wherein the **components** including a first **portion** of an assay strip and a wicking **portion**, the wicking **portion** having a lower **portion** proximal to the base of the container so that, in use, in the container having urine, the urine wicks solely up the wick portion until it reaches an overlapped **portion** of the wicking portion and the first **portion** of the assay strip and thereafter flows upwards in the first **portion** of the assay strip, wherein in use the action of the urine wicking solely upwardly along the wicking **portion** in an upward direction in the container from the base towards the top, and thereafter flows upwards in the first **portion** of the assay strip.

Dependent claim 68 covers **components** where the wicking **portion** is a lower **portion** proximal to the base of the container and a length extending up to the assay strip, whereby the urine flow in the wicking is wicking solely upwardly through the lower **portion** of the wicking material until it reaches the overlapped first **portion** of the assay strip.

Dependent claim 69 covers **components** where the urine flow in the wicking consists of wicking up through the wicking portion until it reaches the overlapped **portion** of the wicking portion and the first portion of the assay strip.

Dependent claim 70 covers **components** where in use, the first **portion** of the assay strip and the first portion of the wicking is located in an elevated position above the base.

Dependent claim 71 covers **components** where in use, the first **portion** of the assay strip and the first portion of the wicking is located in an elevated position above the base.

Dependent claim 72 covers **components** where the first **portion** of the assay strip and the first portion of the wicking are located in an elevated position above the base.

Dependent claims 73-75 covers **components** there is a second **portion** of the assay strip joined to the first **portion** of the assay strip.

Rejections of the prior submitted claims under 35 USC 102 and 35 USC 103

These rejections in light of MacKay and Klimov are rendered moot by the amendments made to the claims.

Specifically, MacKay is simply a test strip holder. There is nothing remotely indicating the relationship of the wick, assay strip and other features in the sense of being upright in a container of the nature of the present invention. In use, the action of the urine **consists of** wicking solely upwardly along the wicking **portion** in an upward direction in the container from the base towards the top.

Klimov indeed is exactly the opposite configuration of the presently claimed invention. It is a construction where the urine flow is downwards. It is the exact problems of this configuration and system, namely flooding, which the present invention is directed at overcoming. The Klimov technology is illustrated as www.varian-onsite.com/docs/testcup.html.

Rejections under 35 U.S.C. § 103 are Inappropriate

KSR Applies to the Instant Application

The Applicant submits that there is no teaching, suggestion, motivation test promulgated by United States Court of Customs and Patent Appeals and adopted by the Federal Circuit. *Application of Bergel*, 292 F.2d 955, 956-957, 48 C.C.P.A. 1102, 1961 Dec. Comm'r Pat. 504 (1961). The Applicant recognized, however, that the current authority on matters of obviousness must square with the Supreme Court's recent decision in *KSR Int'l v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007). Accordingly, although the teaching, suggestion, motivation test is still recognized under *KSR*, the test is largely subsumed by the more general principles laid out in *KSR*. Indeed, in any given application, the combination of elements "must do more than yield a predictable result." *Id.* at 1740. Nevertheless, combining elements "in an unexpected and fruitful manner" is sufficient to render an invention non-obvious. *Id.*

Any Teaching or Combination of References Used by the Examiner is Improper

KSR provides guidance with respect to the combination of references used to reject a patent application on the ground of obviousness. According to *KSR*: "Although **common sense** directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, **it can be important to identify a**

reason that would have **prompted** a person of ordinary skill in the relevant field **to combine the elements** in the way the claimed new invention does.” *KSR* at 1741 (emphasis added).

More importantly, “a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.**” *Id.* (emphasis added).

In *KSR*, the Supreme Court addressed such logic in obviousness-type rejections. Importantly, *KSR* specifically forbids obviousness rejections simply because each element was independently known in the prior art. The art cited against the instant application falls into this rubric because they are nothing more than a string of unrelated references showing each of the claimed elements with tenuous logic to support their combination.

The Examiner has failed in his burden to explain any compelling reason why a person of ordinary skill would have combined these references.

No Reasonable Expectation of Success Can Be Inferred from the Combination of References Asserted by the Examiner

Reasonable Expectation Standard Reaffirmed Post-KSR

The Federal Circuit stated “obviousness does not require absolute predictability of success . . . [a]ll that is required is a reasonable expectation of success.” *In re O’Farrell*, 853 F.2d 894, 903-04; 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988). Thus, if a reasonable expectation of success is derived from a reference or combination of references, an invention may be rendered obvious. Conversely, where no reasonable expectation of success is derived, an obviousness rejection is improper. *Id.*

More specifically, *O’Farrell* provides general guidance as to when an invention falls under the reasonable expectation of success rubric, which was subsequently reaffirmed by the Federal Circuit post-*KSR* in *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, 491 F.3d 1342, 1364; 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007). According to the Federal Circuit, “an invention would not be invalid for obviousness if the inventor would have been motivated ‘to **vary all**

parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the **prior art gave either no indication** of which parameters were critical or **no direction** as to which of many possible choices is likely to be successful.” *Id.* at 1364, *quoting Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865 (Fed. Cir. 2006) (emphasis added).

In a secondary test posited by the Federal Circuit in *Pharmastem*, the court stated “[l]ikewise, an invention would **not be deemed obvious** if **all that was suggested** ‘was to **explore a new technology or general approach** that seemed to be a **promising field of experimentation**, where the **prior art gave only general guidance** as to the particular form of the claimed invention or how to achieve it.” *Id.*, *quoting Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157, 1165, 77 U.S.P.Q.2d 1865 (Fed. Cir. 2006) (emphasis added).

No Reasonable Expectation of Success Where Numerous Possible Choices or Requirement to Vary All The Parameters

Using the first of the standards promulgated by the Federal Circuit, the combination of references cited by the Examiner against the claims have no reasonable expectation of success because the prior art references give no indication of critical parameters or direction as to how to achieve the claimed invention. Using any one of the prior art as the starting point to arrive at the claimed references cited against the instant application would require numerous choices in direction and experimentation, as well as variance of many parameters to arrive at the claimed invention.

For the reasons stated above, the prior art references cited against the claims also fail the second standard promulgated by the Federal Circuit. An invention is not obvious if all that was suggested is to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it. *Pharmastem* at 1364. In other words, the combination of references must give specific guidance to arrive at the claimed invention.

More specifically, the prior art references cited against the instant claims include references directed to different fields. These prior art references alone give no more than general guidance to the instant problem and claimed solution, and arguably do not give any guidance whatsoever.

In fact, the combination of these references makes sense **only** when viewed in the context of the specification and claims. Alone, they don't get a person of ordinary skill in the art any closer to an expectation of success because they simply don't have enough guidance, even when combined, to guide a person of ordinary skill in the art to the claimed result without significant detective work.

Claims 67 to 75 are not obvious in light of the Claims of U.S. Patents 6,379,620, 6,805,837 and 6,805,838

The Examiner has rejected all claims under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent Numbers 6,379,620, 6,805,837 and 6,805,838.

The Examiner asserts that although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims differ only nominally from the patented claims of the '620, '837 and '838 patents.

Applicant respectfully disagrees with the Examiner. The claims are patentably distinct such that an obviousness-type double patenting rejection is without merit. The claims are patentably distinct from the claims in the '620, '837 and '838 patents. This renders a Terminal Disclaimer, in fact, unnecessary and unwarranted.

The submitted Claims 67 to 75 are independent, and it is submitted that each of these claims have patentable distinctiveness over the claims in the '620, '837 and '838 patents.

It is respectfully submitted that each of the Claims 67 to 75 of the present patent application have patentable distinct limitations that are absent from each of the claims of the '620, '837 and '838 patents.

Features listed in the above claims can in no manner be considered disclosed, taught, suggested or rendered obvious to one skilled in the art.

There are two declarations attached. Although these declarations are related to the distinctions over the '620 patent, they are submitted to be applicable to the issues herein. The Examiner is referred to the Third Supplemental Declaration of Barry Tydings in Support of Patentability of Claims Over the Claims of Patent No. 6,379,620 ("Tydings Decl."), attached hereto as Appendix A, and Declaration of James G. Hipple II in Support of Patentability of Claims Over the Claims of Patent No. 6,379,620 ("Hipple Decl."), attached hereto as Appendix B. These declarations were filed in the related reexamination application 90/007,820 (Patent No. 6,805,838) and 90/007,813 (Patent No. 6,805,837).

There is a significant patentable difference which has been pointed out the Examiner, which has apparently not been fully appreciated. When the urine wicks **over the top** through the wicking there is the likelihood of flooding the assay strip with excess urine. This is in the **claims** of the '620 patent. Thus by having the urine wick up the wicking and up the strip - and not over the top through the wicking - there is an important control to prevent the flooding of the assay strip. This is the effect of the claims now presented in this reexamined patent application.

The Claims 67 to 75 are simply not obvious in view of the prior art **claims** of '620, '837 and '838 patents.

It is necessary to examine as the prior art **each of the specific claim features** claimed in the '620, '837 and '838 patents and it will be seen that there is no way that the claims of these patents have any teaching of the features of Claims 67 to 75.

For instance, claims 1 through 6 of the '620 patent each require a wicking means provided on a back surface of said liquid impermeable layer separated from the assay strip by the liquid impermeable layer with one **portion** of said wicking means extending over a top edge of said liquid impermeable layer with said **portion** of said wicking means overlapping a top **portion** of said assay strip.

Pending Claims 67 to 75

As stated above, these claims variously require

- an overlapped **portion** of the wicking **portion** and the assay strip **portion**
- thereafter flows upwards in the assay strip,
- in use, the container is in an upright position with a top through which urine is introduced into the container,
- in use the action of the urine consists of wicking solely upwardly along the wicking **portion** in an upward direction in the container from the base towards the top.

These characteristics are simply not found or suggested in the language of the patent **claims** in the '620, '837 or '838 patents. The following tables are representative and highlight these different claim features. It will be understood that the presently submitted claims 67-75 are clearly patentably distinguishable.

'837 Patent Claim 1	'620 Patent Claim 1	'620 Patent Claim 5
1. An assaying device for in field urine analysis comprising:	1. An assaying device for in field urine analysis comprising:	5. An assaying device for in field urinalysis comprising:
a container having an opening for collecting a urine sample,	a transparent container means having an opening for collecting a urine sample;	a transparent container means having an opening for collecting a urine sample therein;
a base for the container, and a wall for the container;		
a cover for sealing the opening of the container;	a cover means for sealing said opening of said container means; and	a cover means for sealing said opening of said container means; and
an assay assembly with the container for chemically analyzing the urine sample,	an assay assembly provided in said container means for chemically analyzing said urine sample, said assay assembly comprising;	an assay assembly provided in said transparent container means for chemically analyzing said urine sample, said assay assembly comprising:
	a liquid impermeable backing;	a liquid impermeable layer;

'837 Patent Claim 1	'620 Patent Claim 1	'620 Patent Claim 5
the assay assembly having at least one assay strip provided for the assembly and being in liquid transmittable contact with wicking,	at least one assay strip provided on a front surface of said liquid impermeable backing facing outwardly and viewable through said transparent container means;	at least one assay strip provided on a front surface of said liquid impermeable layer facing outwardly and viewable through said transparent container means;
the wicking having a lower portion proximal to the base of the container and being for communication with urine in the container such that, in use, when there is urine in the container and the container is in an upright position with the opening above the base, the urine wicks up the wicking to the assay strip thereby to permit a flow of urine in the container to the assay strip and wicks up the strip; and the assay strip being directed adjacent to the wall of the container thereby to be readable through the container wall.	a wicking means provided on a rear surface of said liquid impermeable backing separated from said assay strip by said liquid impermeable backing with one portion of said wicking means extending over a top edge of said liquid impermeable backing and overlapping a top portion of said assay strip;	at least one longitudinally extending wicking means provided on a back surface of said liquid impermeable layer separated from said assay strip by said liquid impermeable layer with one portion of said wicking means extending over a top edge of said liquid impermeable layer with said portion of said wicking means overlapping said assay strip; and
	a front cover means provided on said front surface of said liquid impermeable backing, said front cover means sealing said assay strip to said liquid impermeable backing at a bottom and two sides of said assay strip; and	a cover means provided on said assay strip and wicking means for sealing said wicking means and assay strip from liquid contact with said urine sample except at one end portion of said wicking means.
	a rear cover means provided on said rear surface of said liquid impermeable backing for sealing said wicking means to said liquid impermeable backing at two sides of said wicking means.	

'838 Patent Claim 2	'620 Patent Claim 2
2. An assay assembly for chemically analyzing a urine sample, the assay assembly comprising:	2. An assay assembly for chemically analyzing a urine sample, said assay assembly comprising:
a container;	
a backing;	a liquid impermeable backing;
a wicking;	a wicking means provided on a rear surface of said backing
	<i>(over the top wicking element moved below)</i>
at least one assay strip provided on a front surface of the backing and being in liquid transmittable contact with the wicking,	at least one assay strip provided on a front surface of said liquid impermeable backing;
the wicking having a lower portion proximal to the base of the container so that, in use, in the container having urine, the urine wicks solely up the wick to the assay strip, and	with one portion of said wicking means extending over a top edge of said liquid impermeable backing with said portion of said wicking means overlapping a top portion of said assay strip;
in the use, the container is in an upright position with a top through which urine is introduced into the container, and	
a base for the container;	
a front cover provided on the front surface of the backing for locating the assay strip to the backing; and the backing together with the front cover and the assay strip being located adjacent a wall of the container and extending from a position proximal to the top of the container to a position proximal to the bottom of the container so that in use the urine wicks solely upwardly in the container from the base towards the top.	a front cover means provided on said front surface of said liquid impermeable backing for sealing said assay strip to said liquid impermeable backing at a bottom and two sides of said assay strip; and

'838 Patent Claim 2	'620 Patent Claim 2
	a rear cover means provided on said rear surface of said liquid impermeable backing for sealing said wicking means to said liquid impermeable backing at two sides of said wicking means.

The Claims 58 to 65 Cover Features Which Are Patentably Distinct From the Claims of the Prior Patents

The limitations emphasized in bold in the claim portions quoted above, as well as other limitations in claims, are simply not found or suggested in the language of the patent claims 1-6 in the prior patents or rendered obvious to one skilled in the art. (Third Suppl. Tydings Decl. and Hipple Decl.) Because these distinguishing features are not set forth or suggested in the prior patent claims, it is respectfully submitted that claims are, in fact, patentably distinct from the patent claims. These claims are simply not obvious in view of the cited prior art claims of the patents before the Examiner.

In the Third Supplemental Declaration of Barry Tydings, Barry Tydings, a person skilled in the art with many years of work in this technology, explains that:

“ 3. With the wick system of the claims of the '620 patent we experienced problems with wicking, migration and flooding of urine on the wick and the assay strip. If there was too much urine in the cup, the urine on the wicking would flood the assay strip. This would wipe out the antibodies and antigens on the assay strip, which negated the test. If there was not enough urine in the cup, the urine would be insufficient to wick over the top and therefore would not activate the assay test strip. Either way there was no consistent migration of the urine to the wicking and the test strips. The test cups with this technology are not scientifically or technically consistent to provide for acceptable testing.

4. The technology of the claims of the present application are directed to an invention which avoids these problems with wicking over the top of the backing, namely the

subject of the claims of the '620 patent. The claims of the present application represent an important advance scientifically and technically over the technology of the claims of the '620 patent, since they cover an assay where the urine flow is contrary to having the urine flow with the wicking extending over the top.

8. In view of my experience in the field of such assays, I believe that changing the construction from over-the-top wick construction to the construction of wicking up the wick and up the strip was not an obvious change.

9. Prior to my inventing the up the wick/up the strip construction, there were no competitors in this field. After this up the wick/up the strip construction was developed, many competitors entered the field, because at that time I had developed a new and non-obvious construction which worked effectively and for which there was a substantial commercial demand, and this invented construction solved the previously unsolved need.

10. My up the wick/up the strip construction of urine test cup is an important advance which took ingenuity. It was not merely a substitution of alternatives, or an expected result. Before I thought of this "up the wick/up the strip" construction, I had tried many different techniques to create a stable consistent product with the over the top wicking. I did not remotely even think of the reverse construction, namely the "up the wick/up the strip" construction would obviate all the prior problems. Simply stated, it was not an obvious solution.

11. I was forced to abandon the wicking over the top construction after many trials, experiments and efforts to increase its stability and reliability, none of which worked.

12. It was not readily obvious to me at that time, that the up the wick/up the strip construction could work, and solve the problems being experienced with the wicking over the top construction. It would not have been obvious to anyone of skill in the art at the time and who was actually struggling with the real problems of making a workable reliable product, that this totally different construction would actually work and solve those problems.

13. The up the strip wicking functions differently from a down the wick flow of urine, which was a characteristic of the

over the top wicking construction. It would not have been obvious to make the change of flow and appreciate that it would function.

14. I consider that the up the wick/up the strip construction would not have been obvious at the time in the light of my prior over the top wick construction. It would have taken ingenuity to achieve the successful urine cup testing system with the up the wick/up the strip construction.”

(Tydings Decl., ¶¶ 3, 4, 8, 9, 10, 11, 12, 13 and 14)

Tydings is a person of considerable skill in this technology field with over 9 years of experience and has been responsible for the design, manufacture and sale of over 4,000,000 cups using the technology of the present ‘837 patent. (Tydings Decl., ¶¶ 5, 6 and 7.)

In the Declaration of James G. Hipple II, James Hipple, a person skilled in the art with many years of work in this technology, explains that:

“ 6. I am a person of ordinary skill in the art of urine drug testing cups. Even though I have been involved in many aspects of these kinds of test cups since 1997, it would not have, and did not occur to me that having the urine wick solely up the wicking, or up the assay strip would solve all the prior problems with cups. The up the wick/up the strip construction is an important advance scientifically and technically to the over the over the top wicking of the prior technology. Such cups are far superior to the prior problematic over the top wicking construction.

7. Changing the construction from over-the-top wick construction to the construction of wicking up the wick and up the strip was not an obvious change, and it was an important advance which took ingenuity. It would not have been obvious to anyone of skill in the art at the time and who was actually struggling with the real problems of making a workable reliable product, that this totally different construction would actually work and solve those previously unsolved problems.

8. I worked with Barry Tydings in 1998 and 1999 explaining the problems that his cups were presenting to my customers. For several months, we brainstormed about solutions to the problem: These included using different qualities and quantities of adhesive tape to change the bonding and securing

characteristics of the assay strip and wicking material to each other and to the underlying substrate holding them in the assay cup. We also considered the possibility of different thicknesses of wicking material to facilitate the better and more consistent urine flow and the overall cup construction modifications. The assembly of the different components was largely manual, and that was problematic. We investigated the possibility of automating the manufacturing, but this proved to be prohibitively expensive. No ready solution appeared to us.

10. The only competitor cup we could look at for ideas was the Roche cup, (Galloway Patent No. 5,403,551) but this worked on a different principle, namely the down the strip urine flow. There was nothing that led us to the solution that Barry Tydings ultimately came up with, namely the up the wick/up the strip construction.

11. The up the wick/up the strip construction solved the problems being experienced with the wicking over the top construction. The up the strip wicking functions differently from a down the wick flow of urine, which was a characteristic of the over the top wicking construction. It would not have been obvious to make the change of flow and appreciate that it would function and be operable.”

(Hipple Decl., ¶¶ 6, 7, 8, 10 and 11)

Terminal Disclaimer

The Terminal Disclaimer requirement has not been addressed in this response since it is believed to have been rendered moot by the above submission. Should the Applicant be incorrect therein, the Applicant reserves the right to readdress this fully at a later time.

Conclusion

Accordingly, the Claims 67 to 75 now submitted are patentably distinct such that an obviousness-type double patenting rejection is without merit and should be withdrawn.

It is respectfully submitted that all of the Examiner's objections have been successfully traversed and that the application is now in order for allowance. Accordingly, reconsideration of the application and allowance thereof is courteously solicited.

Authorization is hereby given to charge any additional fees or credit overpayment to Deposit Account No. 50-2638. Please reference Attorney Docket Number 056990-010601 when charging any payments or credits in connection with this application.

Respectfully submitted,



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